



News Release

Attorney General Robert E. Cooper, Jr.

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ELI LILLY TO PAY MORE THAN \$1.4 BILLION FOR OFF- LABEL DRUG MARKETING

Tennessee has joined with other states and the federal government in an agreement in principle with Eli Lilly and Company, to settle allegations it engaged in off-label marketing that improperly promoted the anti-psychotic drug, Zyprexa, Attorney General Bob Cooper announced today.

Eli Lilly will pay the states and the federal government a total of \$800 million in damages and penalties to compensate Medicaid and various federal healthcare programs for harm suffered as a result. Tennessee's share of the agreement totals \$11.3 million for restitution and penalties.

Zyprexa is an antipsychotic drug used to treat certain psychological disorders. Between September 1999 and Dec. 31, 2005, Eli Lilly promoted the sale and use of Zyprexa, primarily through a marketing campaign called "Viva Zyprexa," for certain uses which the Food and Drug Administration had not approved. The "Viva Zyprexa" campaign promoted Zyprexa not only to psychiatrists, but also to primary care physicians, for such unapproved uses as the treatment of depression, anxiety, irritability, disrupted sleep, nausea and gambling addiction.

During the campaign, Eli Lilly also provided incentives to physicians and other health care professionals to induce physicians to prescribe Zyprexa for children and adolescents, dementia patients in long term care facilities, and in unapproved dosage amounts. None of these uses were medically acceptable for reimbursement by state Medicaid programs.

This case was handled by the Tennessee Attorney General's Office, the Tennessee Bureau of Investigation Medicaid Fraud Control Unit and the TennCare Bureau.

"We hope this will lead to better practices and greater accountability in this segment of the healthcare industry," Attorney General Cooper said.

"This is a significant recovery for our Medicaid program," said Darin Gordon, TennCare Director and Deputy Commissioner of the Department of Finance and Administration.

As part of the settlement, Eli Lilly will enter a Corporate Integrity Agreement with the United States Department of Health and Human Services, Office of the Inspector General which will closely monitor the company's future marketing and sales practices.

This settlement is based on four qui tam cases that were filed or consolidated in the United States District Court for the Eastern District of Pennsylvania by various relators - private parties that filed actions under state and federal false claims statutes.

In addition, the United States Attorney for the Eastern District of Pennsylvania has filed a criminal Information in United States District Court charging Eli Lilly with a misdemeanor violation of the

Food, Drug and Cosmetic Act. In a plea agreement filed with the Court, Eli Lilly has agreed to pay a \$615 million criminal fine to resolve the charge.